

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL SEARCH REPORT**  
(PCT Article 18 and Rules 43 and 44)

|   |   |   |
|---|---|---|
| Applicant's or agent's file reference<br><b>9577-58 KAM</b> | <b>FOR FURTHER ACTION</b> <div style="text-align: right; font-size: small;">see Form PCT/ISA/220<br/>as well as, where applicable, item 5 below</div> |   |
| International application No.<br><b>PCT/CA2007/000548</b>   | International filing date ( <i>day/month/year</i> )<br><b>03 April 2007 (03-04-2007)</b>  | (Earliest) Priority date ( <i>day/month/year</i> )<br><b>03 April 2006 (03-04-2006)</b> |
| Applicant<br><b>ODIDI, ISA ET AL</b>                        |   |   |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

- a. With regard to the language, the international search was carried out on the basis of:
- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
- b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).
- c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I

2. ☒ Certain claims were found unsearchable (see Box No. II)

3. ☒ Unity of invention is lacking (see Box No. III)

4. With regard to the title,

☒ the text is approved as submitted by the applicant

☐ the text has been established by this Authority to read as follows :

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. 1

☐ as suggested by the applicant

☒ as selected by this Authority, because the applicant failed to suggest a figure

☐ as selected by this Authority, because this figure better characterizes the invention

b. ☐ none of the figures is to be published with the abstract

# INTERNATIONAL SEARCH REPORT

International application No.  
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## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons :

1. ☒ Claim Nos. : 51 and 52  
because they relate to subject matter not required to be searched by this Authority, namely :  
  
Claims 51 and 52 are directed to a method for treatment of the human or animal body by surgery or therapy, are not required to be searched nor is a written opinion required by this Authority. Regardless, this Authority has established a written opinion based on the alleged effect or purpose/use of the product defined in claims 51 and 52.
2. ☐ Claim Nos. :  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically :
3. ☐ Claim Nos. :  
because they are dependant claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows :

**Group A:** Claims 1-30, 51-56 (in part) and 57-66 are directed to a drug delivery composition comprising extruded spheroids, the spheroids comprising at least one active pharmaceutical ingredient; at least one extrusion-spheronization aid; at least one superdisintegrant; and at least one glidant, at least one lubricant; and/or at least one oil, a method of making the same as well as its use in pharmaceutical and medical fields

**Group B:** Claims 31-50 and 51-56 (in part) are directed to a drug delivery composition comprising coated spheroids having inert spheroids and at least one coating for the spheroids, the coating comprising at least one active pharmaceutical ingredient and at least one superdisintegrant and its use in pharmaceutical and medical fields.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim Nos. :
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim Nos. :

**Remark on Protest** ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.  
☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.  
☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/CA2007/000548

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC: *A61K 9/54* (2006.01) , *A61J 3/00* (2006.01) , *A61K 9/24* (2006.01)  
According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC: *A61K 9/54* (2006.01) , *A61J 3/00* (2006.01) , *A61K 9/24* (2006.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)  
Delphion, Canadian Patent Database, Goggle Scholar and Scopus

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No.      |
|-----------|---|----------------------------|
| X         | US 6673367 (Euro-Celtique), 06 January 2004<br>The whole document   | 1-66                       |
| X         | US 2003/0215507 (Wyeth), 20 November 2003<br>The whole document   | 11-21 and 22-30 (in part)  |
| X         | US 6558704 (Gruenenthal GmbH), 06 May 2003<br>The whole document  | 1-66                       |
| X         | US 2002/0002147 (R. Abramowitz), 03 January 2002<br>Paragraphs [0008]-[0010], [0012]-[0014] and claims  | 11-21 and 22-30 (in part)  |
| X         | US 5049394 (E. R. Squibb & Sons, Inc) 17 September 1991<br>The whole document   | 1-11 and 22-30 (in part)   |
| X         | WO 2004/056354 (Ranbaxy Laboratories Limited), 8 July 2004<br>The whole document  | 11-21 and 22-30 (in part)  |
| X         | WO 02/30398 (Euroceltique S.A.), 18 April 2002<br>Page 6, lines 3-6; page 7, lines 7-12 and 23-29; page 9, lines 6-10; page 16, lines 9-15; page 17, lines 15-16; and claims 1-14 | 11-212 and 22-30 (in part) |

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

|   |  |
|---|--|
| * Special categories of cited documents :   | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  |
| "A" document defining the general state of the art which is not considered to be of particular relevance  | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone   |
| "E" earlier application or patent but published on or after the international filing date   | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "&" document member of the same patent family  |
| "O" document referring to an oral disclosure, use, exhibition or other means  |  |
| "P" document published prior to the international filing date but later than the priority date claimed  |  |

Date of the actual completion of the international search  
16 May 2007 (16-05-2007)

Date of mailing of the international search report  
27 July 2007 (27-07-2007)

Name and mailing address of the ISA/CA  
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Authorized officer  
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**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

International application No.  
**PCT/CA2007/000548**

| Patent document<br>Cited in the Search<br>Report | Publication<br>Date | Patent Family<br>Member(s) | Publication<br>Date |
|--|---------------------|----------------------------|---------------------|
| US6673367  | 06-01-2004          | AU2371200 A                | 03-07-2000          |
|  |                     | CA2355644 A1               | 22-06-2000          |
|  |                     | EP1140088 A1               | 10-10-2001          |
|  |                     | JP2002532426T T            | 02-10-2002          |
|  |                     | US7083808 B2               | 01-08-2006          |
|  |                     | WO0035450 A1               | 22-06-2000          |
| US2003215507                                     | 20-11-2003          | AT237320T T                | 15-05-2003          |
|  |                     | AT257011T T                | 15-01-2004          |
|  |                     | AU727653B B2               | 21-12-2000          |
|  |                     | AU747978B B2               | 30-05-2002          |
|  |                     | AU1300399 A                | 24-05-1999          |
|  |                     | AU1640097 A                | 02-10-1997          |
|  |                     | BG104397 A                 | 28-02-2001          |
|  |                     | BR9701304 A                | 29-09-1998          |
|  |                     | BR9813179 A                | 22-08-2000          |
|  |                     | CA2199778 A1               | 25-09-1997          |
|  |                     | CA2305242 A1               | 14-05-1999          |
|  |                     | CN1090018C C               | 04-09-2002          |
|  |                     | CN1278165 A                | 27-12-2000          |
|  |                     | CN1403077 A                | 19-03-2003          |
|  |                     | CY2442 A                   | 12-11-2004          |
|  |                     | CZ291637 B6                | 16-04-2003          |
|  |                     | CZ20001659 A3              | 17-10-2001          |
|  |                     | DE69727000D D1             | 05-02-2004          |
|  |                     | DE69727000T T2             | 09-06-2004          |
|  |                     | DE69813602D D1             | 22-05-2003          |
|  |                     | DE69813602T T2             | 06-11-2003          |
|  |                     | DK797991T T3               | 05-04-2004          |
|  |                     | DK1028718T T3              | 28-07-2003          |
|  |                     | EE4577 B1                  | 15-02-2006          |
|  |                     | EP0797991 A1               | 01-10-1997          |
|  |                     | EP1028718 A2               | 23-08-2000          |
|  |                     | EP1331003 A1               | 30-07-2003          |
|  |                     | ES2196620T T3              | 16-12-2003          |
|  |                     | ES2210454T T3              | 01-07-2004          |
|  |                     | HK1029056 A1               | 21-11-2003          |
|  |                     | HR20000213 A2              | 31-12-2000          |
|  |                     | HU224617 B1                | 28-11-2005          |
|  |                     | HU225238 B1                | 28-08-2006          |
|  |                     | ID26317 A                  | 14-12-2000          |
|  |                     | IL120382 A                 | 24-06-2003          |
|  |                     | IL135457D D0               | 20-05-2001          |
|  |                     | IL151450 A                 | 31-08-2005          |
|  |                     | IN187337 A1                | 30-03-2002          |
|  |                     | JP10007552 A               | 13-01-1998          |
|  |                     | JP2001521892T T            | 13-11-2001          |
|  |                     | MA24691 A1                 | 01-07-1999          |
|  |                     | NO320355B B1               | 28-11-2005          |
|  |                     | NO20002126 A               | 04-05-2000          |
|  |                     | NO20050379 A               | 26-09-1997          |
|  |                     | NZ314442 A                 | 29-06-1999          |
|  |                     | NZ504460 A                 | 31-01-2003          |
|  |                     | PL188444B B1               | 28-02-2005          |
|  |                     | PL341141 A1                | 26-03-2001          |
|  |                     | PT797991T T                | 31-05-2004          |
|  |                     | PT1028718T T               | 31-07-2003          |

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|               |            |                 |            |
|---------------|------------|-----------------|------------|
|               |            | RU2176912 C2    | 20-12-2001 |
|               |            | SI797991T T1    | 30-04-2004 |
|               |            | SI1028718T T1   | 31-08-2003 |
|               |            | SK30197 A3      | 08-10-1997 |
|               |            | SK6472000 A3    | 07-11-2000 |
|               |            | TR9700190 A2    | 21-10-1997 |
|               |            | TR200001232T T2 | 21-12-2000 |
|               |            | TW493993B B     | 11-07-2002 |
|               |            | TW555568B B     | 01-10-2003 |
|               |            | UA77145 C2      | 15-11-2006 |
|               |            | US6274171 B1    | 14-08-2001 |
|               |            | US6403120 B1    | 11-06-2002 |
|               |            | US6419958 B2    | 16-07-2002 |
|               |            | US2002197307 A1 | 26-12-2002 |
|               |            | US2006062843 A1 | 23-03-2006 |
|               |            | US2006067999 A1 | 30-03-2006 |
|               |            | US2006068000 A1 | 30-03-2006 |
|               |            | US2006068001 A1 | 30-03-2006 |
|               |            | US2006068002 A1 | 30-03-2006 |
|               |            | US2006068017 A1 | 30-03-2006 |
|               |            | CZ20023003 A3   | 13-11-2002 |
|               |            | EE200200564 A   | 15-06-2004 |
|               |            | EP1267879 A2    | 02-01-2003 |
|               |            | HU0302631 A2    | 28-11-2003 |
|               |            | IL151475D D0    | 10-04-2003 |
|               |            | JP2003528905T T | 30-09-2003 |
|               |            | LT5045 B        | 25-08-2003 |
|               |            | LV12939 B       | 20-04-2003 |
|               |            | MXPA02009534 A  | 14-05-2003 |
|               |            | NO20024645 A    | 27-09-2002 |
|               |            | NZ522250 A      | 24-09-2004 |
|               |            | US2006068018 A1 | 30-03-2006 |
|               |            | US2006073201 A1 | 06-04-2006 |
|               |            | WO9922724 A2    | 14-05-1999 |
|               |            | RU2221553 C2    | 20-01-2004 |
|               |            | SK2854238 B6    | 04-01-2007 |
|               |            | US6558704 B1    | 06-05-2003 |
|               |            | ZA200000169 A   | 07-08-2000 |
| US20020002147 | 03-01-2002 | AR027748 A1     | 09-04-2003 |
|               |            | AU4959101 A     | 15-10-2001 |
|               |            | BG107157 A      | 30-06-2003 |
|               |            | BR0109602 A     | 29-06-2004 |
|               |            | CA2404687 A1    | 11-10-2001 |
|               |            | CN1187052C C    | 02-02-2005 |
|               |            | ZA9702403 A     | 21-09-1998 |
| US5049394     | 17-09-1991 | CA1334074 C     | 24-01-1995 |
|               |            | DE3830749 A1    | 30-03-1989 |
|               |            | FR2620332 A1    | 17-03-1989 |
|               |            | GB2209669 A     | 24-05-1989 |
|               |            | IT1227336 B     | 08-04-1991 |
|               |            | JP1156913 A     | 20-06-1989 |
|               |            | US5049394 A     | 17-09-1991 |

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PCT/CA2007/000548

|              |            |  |  |
|--------------|------------|--|--|
| US6558704    | 06-05-2003 | AU7642808 B2<br>CA2295470 A1<br>CN1161108C C<br>CZ291936 B6<br>NZ502264 A<br>PL337864 A1<br>ZA9810081 A<br>DE19901692 A1<br>EP1020181 A1<br>HU0000141 A2<br>IL134079 A<br>JP2000212068 A<br>PL366089 A1<br>RU2239435 C2<br>SK12822002 A3<br>US7135465 B2<br>WO0174329 A2 | 14-08-2003<br>18-07-2000<br>11-08-2004<br>18-06-2003<br>30-11-2001<br>31-07-2000<br>04-05-2000<br>20-07-2000<br>19-07-2000<br>28-12-2000<br>15-12-2004<br>02-08-2000<br>24-01-2005<br>10-11-2004<br>04-02-2003<br>14-11-2006<br>11-10-2001 |
| WO2004056354 | 08-07-2004 | AU2003288604 A1<br>BR0317567 A<br>CA2511208 A1<br>CN1744889 A<br>EP1596849 A1<br>IN192381 A1<br>JP2006512358T T<br>RU2005121999 A  | 14-07-2004<br>22-11-2005<br>08-07-2004<br>08-03-2006<br>23-11-2005<br>10-04-2004<br>13-04-2006<br>20-01-2006   |
| WO0230398    | 18-04-2002 | AU9208601 A<br>BR0114633 A<br>CA2433186 A1<br>CN1489455 A<br>DE20121853U U1<br>EP1324752 A2<br>GB0025208D D0<br>IL155293D D0<br>JP2004510812T T<br>MXPA03003235 A<br>US2004052846 A1<br>US2007071820 A1  | 22-04-2002<br>10-02-2004<br>18-04-2002<br>14-04-2004<br>31-07-2003<br>09-07-2003<br>29-11-2000<br>23-11-2003<br>08-04-2004<br>15-10-2003<br>18-03-2004<br>29-03-2007   |